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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,310	07/17/2003	Janice North	273012013101	4352

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,310	NORTH ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment and Terminal Disclaimer filed September 28, 2004 have been received and entered into the application. Accordingly, claim 1 has been amended.

In view of the amendment to claim 1 and the acceptable nature of the Terminal Disclaimer, the claim rejections set forth in the previous Office action dated March 25, 2004 under 35 U.S.C. § 112, second paragraph and the judicially-created doctrine of obviousness-type double patenting are withdrawn.

Assignment of Application

The Examiner acknowledges applicants' statement at page 5 of their amendment that the current application, being a continuation of U.S. Serial No. 10/199,662, is assigned to QLT, Inc. QLT, Inc. is the same assignee as that of U.S. Patent Application Publication 2003/0083649 which forms the basis of the rejections set forth herein under 35 U.S.C. 102(e) and 103.

Claim Rejection - 35 USC § 102

Claims 1, 5-11, 13, 15, 16 and 18-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Margaron et al., (U.S. Patent Application Publication No. 2003/0083649), already of record, for the reasons of record as set forth in the previous Office action at pages 3-4, as applied to claims 1, 5-11 and 13.

Claims 15, 16 and 18-22 are newly rejected. Claim 15 requires that the volume of interstitial fluid in the eye of a subject having macular edema is reduced by the steps of (1) administering an effective amount of a photosensitizer (PS) to said subject, and (2) irradiating said subject's macula with light having a wavelength absorbed by said PS. Margaron et al. do

not disclose that the volume of interstitial fluid is reduced. However, as set forth in the previous Office action, Margaron et al. do disclose each and every other limitation of the present claims. Because in both the Margaron et al. reference and applicants' claims, the same photosensitizer is irradiated by the same light source having the same wavelength in the same anatomical tissue and in the same host; and because the subject in both Margaron et al. and applicants' claims would necessarily have a given volume of interstitial fluid in the eye, it must be concluded that a reduction in the volume of interstitial fluid in the eye of the subject of Margaron et al. would inherently occur, whether expressly disclosed by Margaron et al. or not.

Legal Standard for Anticipation Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102(b), a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genetech, Inc.,* 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue,* 766 F2d531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). To anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum,* 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber,* 128 F.3d 1473, 1477, 44 U.S.P.Q. 1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.,* 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). To inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile*, 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art

recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Applicants' Arguments

Applicants' arguments at pages 6 and 7 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, applicants have argued that because Margaron discloses "the area exposed to low dose PDT should overlap with, and sometimes may be, larger than the area exposed [to] radiation under normal dose PDT." Paragraph [0100], the reference does not describe irradiation of the macula itself and thus the present claims are not anticipated.

The Examiner cannot agree because "the area exposed to low dose PDT should overlap with, and sometimes may be, larger than the area exposed [to] radiation under normal dose PDT." provides for irradiation of the same area exposed to radiation under normal dose PDT. This "area" would be the macula itself, as required by the present claims, because in the teaching "which method comprises exposing a target tissue in a subject that has been treated with normal dose PDT treatment to low dose light…" (paragraph [0010]), the "target tissue" would be the macula where the subject is afflicted with diabetic macular edema (paragraph [0012, line 8).

Accordingly, the claims are believed to be properly rejected.

Claim Rejection - 35 USC § 103

Claims 2-4, 12, 14, 17 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margaron et al., (U.S. Patent Application Publication No. 2003/0083649), already of record, for the reasons of record as above and in the previous Office action at pages 4 and 5, as applied to claims 2-4, 12 and 14.

Applicants' arguments at page 7 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

Applicants have argued that because the present application is assigned to the same assignee as Margaron et al., 35 U.S.C. § 103(c.) dictates against the present rejection.

The Examiner cannot agree because "is assigned" is not the standard as set forth in 35 U.S.C. § 103(c.). Rather, 35 U.S.C. § 103(c.) precludes a rejection based on a reference where that reference and applicants' claimed subject matter, at the time the claimed subject matter was made, was owned by the same person or subject to an obligation of assignment to the same person.

In order to overcome this rejection, applicants must submit a statement that the presently claimed subject matter, i.e., the subject matter of claims 2-4, 12, 14, 17 and 23, at the time the claimed subject matter was made, was owned by the same person or subject to an obligation of assignment to the same person. The Office only requires that such a statement be of record and does not require that such a statement be accompanied by a showing of fact.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

November 13, 2004